In the Supreme Court of the United States

OCTOBER TERM, 1968

No. 343

UNITED STATES OF AMERICA, PETITIONER

v.

AN ARTICLE OF DRUG * * * BACTO-UNIDISK * * *

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

REPLY MEMORANDUM FOR THE PETITIONER

Respondent asserts that there is no danger to health from uncertified antibiotic discs, and that the government's witnesses contradicted any claim that patient health might be endangered (Br. in Opp. 3, 5–6).

1. It is undisputed that the results of sensitivity testing with antibiotic discs, such as the Bacto-Unidisk, frequently lead physicians to change from one antibiotic that has been used to initiate therapy to another antibiotic shown by sensitivity testing to be more effective in combating patients' infections. Indeed, Dr. Keefer, respondent's medical witness, said that disc sensitivity testing "is usually employed in patients who have infections—complicated infections—such as urinary tract infections, who are not

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responding to a broad spectrum antibiotic", with the result that "the treatment is frequently changed" (R. 93a).

2. Respondent is in error in stating that two government witnesses were unable to support the proposition that certification of sensitivity discs is needed to avoid a danger to the health of patients (Br. in Opp. 3, 6).

On the very pages of the record it cites (R. 59a, 60a, 64a, and 102a), Dr. Truant testified: that "false readings" would be obtained from improperly prepared discs and that the physician consequently "would not treat the patient properly" (R. 59a); that poor standardization would result in production of discs "of poor quality, which would give misinformation" to the laboratory and the clinician (R. 60a); and that while he could not put his finger on a specific example in which a physician had been misled to the detriment of a patient, he could "recall that there were a number of instances brought to my attention by individuals in the infectious disease department" (R. 64a).

Dr. Lerner was asked on cross-examination whether he thought "the public health was involved" in disc reliability. He replied that he did (R. 102a). While he personally had not seen a case of patient harm from a faulty disc, he had on some occasions discarded disc data as unreliable because it was inconsistent with other information concerning the patient's condition (R. 102a). On the preceding page, not cited by respondent, Dr. Lerner was asked on direct examination about the importance of disc standardization

and reliability. He answered, "I feel that it is vital" (R. 101a). Hospital laboratories, he said, were unable to check discs for performance, and thus had to rely upon the label representations as to their composition and their performance (R. 100a–101a).

3. This record thus confirms the administrative determination that sensitivity disc reliability is essential to the safe and effective use of antibiotic drugs and our contention that antibiotic certification requirements were properly applied to such discs to assure their reliability, after numerous complaints and an extensive administrative investigation (see Pet. 7–8). There was ample basis developed in the rule-making proceedings for the administrative determination that results yielded by a sensitivity test with a disc impregnated with an improper amount of an antibiotic drug, or with a disc which does not properly diffuse its antibiotic drugs into the bacterial growth media, pose a real danger of improper and ineffective therapy with the wrong drug at a critical stage of the patient's course of treatment. As our petition shows, the antibiotic certification procedures were designed to assure the quality and performance characteristics needed to prevent such therapeutic misadventures. The correctness of the decision of the court of appeals, which bars this vital protection for the public health, presents an important question of statutory interpretation warranting review.

Respectfully submitted.

ERWIN N. GRISWOLD,
Solicitor General.

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